# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 16-557V**

Filed: June 23, 2020

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| ASHLEY WALLS and KEVIN WALLS, parents of K.W., a minor,<br><br>Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | PUBLISHED<br><br>DTaP Vaccine; Hib Vaccine; Hepatitis B Vaccine; Pneumococcal (PCV) Vaccine; Immune Thrombocytopenia Purpura ("ITP"). |

*Ronald C. Homer*, Conway, Homer, P.C., for Petitioners
*Mary E. Holmes*, U.S. Department of Justice, Washington, DC, for Respondent

## RULING ON ENTITLEMENT[1]

**Oler**, Special Master:

On May 9, 2016, Ashley Walls ("Ms. Walls") and Kevin Walls ("Mr. Walls") (collectively "Petitioners"), filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program") on behalf of their son K.W. The petition alleges that K.W. developed thrombocytopenia as a result of the Diphtheria-

[1] This ruling will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this ruling will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Tetanus-acellular-Pertussis ("DTaP"), haemophilus influenzae ("Hib"), Hepatitis B ("Hep B"), and pneumococcal ("PCV") vaccines that K.W. received on July 16, 2014. Pet. at 1, ECF No. 1.

Upon review of the evidence in this case, I find that Petitioners have met their burden in showing that the vaccinations K.W. received on July 16, 2014 caused him to develop immune thrombocytopenia purpura ("ITP"). They are therefore entitled to compensation under the Vaccine Act.

## I. Procedural History

Petitioners[3] filed their petition on May 9, 2016.[4] On September 14, 2016, Respondent filed a Rule 4(c) Report, presenting his analysis of Petitioners' claims and concluding this case is not appropriate for compensation under the Vaccine Act. ECF No. 14. Petitioners filed an expert report by Dr. Edwin Forman, Dr. Forman's curriculum vitae ("CV"), and medical literature on April 10, 2017. Exs. 16-17, ECF No. 28. On June 9, 2017, Respondent filed an expert report from Dr. Joan C. Gill. Ex. A, ECF No. 32. Respondent filed Dr. Gill's CV and medical literature cited in her expert report on March 8, 2018. Exs. B1-B6, C, ECF No. 39. Petitioners filed a supplemental expert report from Dr. Forman on April 19, 2018. Ex. 18, ECF No. 44.

An entitlement hearing was originally scheduled for May 31 and June 1, 2018. *See* Pre-Hearing Order on January 31, 2018, ECF No. 38. During a status conference on May 8, 2018, Respondent relayed that his expert Dr. Gill, had fallen ill and could no longer participate as an expert in this case. *See* Scheduling Order on May 8, 2018, ECF No. 47; *see also* Minute Entry on May 8, 2018. Respondent subsequently requested time to file an expert report from another expert. I granted this request. *Id.* On July 21, 2018, Respondent filed an expert report from Dr. John Strouse, M.D., Ph.D., along with his CV and supporting medical literature. Exs. D-F, ECF No. 47. Petitioners filed a supplemental expert report on October 19, 2018. Ex. 20, ECF No. 54.

On February 5, 2019, I issued an Order informing the parties that I intended to rule in favor of Petitioners and encouraged the parties to informally negotiate damages. *See* non-PDF Scheduling Order on February 15, 2019. On February 7, 2019, Respondent conveyed that he was in the process of preparing a supplemental expert report and desired to submit it. *See* Scheduling Order February 7, 2019, ECF No. 56. Respondent filed a supplemental expert report on February 13, 2019. Ex. G, ECF No. 57. On April 26, 2019, the parties filed a joint status report indicating the record was complete and that they were amenable to a Ruling on the Record. ECF No. 59.

On June 25, 2012, Petitioners filed a Motion for Ruling on the Record. ECF No. 61. Respondent filed a Response to Petitioners' Motion on August 27, 2019. ECF No. 62. Petitioners filed a Reply on September 30, 2019. ECF No. 63.

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[3] Ms. Walls was the sole petitioner at the outset of this case. Ms. Walls filed a Motion to Amend/Change Caption on July 29, 2016 with a request to include Mr. Walls (ECF No. 11). I granted the request that same day (ECF No. 12).

[4] This case was initially assigned to now-retired Special Master George Hastings (ECF No. 4), was reassigned to then-Special Master Brian Corcoran on October 10, 2017 (ECF No. 34), and then reassigned to my docket on December 5, 2017 (ECF No. 36).

On April 16, 2020, Petitioners filed summaries of one reference in Dr. Forman's first report (Exhibit 16, Tab D); this reference included two case reports that were in French. Ex. 21. I held a status conference on April 17, 2020 where I informed the parties that I intended to rely on a medical article that had not yet been filed into the record. *See* Court Ex. 1, D.B. Cines, et al., *The ITP Syndrome: Pathogenic and Clinical Diversity*, 113 Blood 26 (June 25, 2009), pp. 6511-21; ECF No. 68-1 (hereinafter "Cines II"). I gave the parties 30 days to indicate whether they wanted to comment on the article. *See* April 17, 2020 Order; ECF No. 68. I also gave Respondent 30 days to respond to Exhibit 21. *See id.* Petitioners requested an extension of time until June 8, 2020 to file their comments. ECF No. 72. I granted Petitioners' request and also extended Respondent's deadline to that same date. Non-PDF Order dated May 18, 2020.

On June 8, 2020, the parties each filed comments to Court Ex. 1. Petitioner's comments were in the form of a statement from Dr. Forman. *See* ECF No. 73. Respondent filed a status report with comments (ECF No. 75) as well as a supplemental Expert Report from Dr. Strouse. Ex. H, ECF No. 74. This matter is now ripe for adjudication.

## II. Medical Records

### A. Pre-Vaccination History

K.W. was born on March 29, 2013. Ex. 3 at 79. Ms. Walls' pregnancy was full term and K.W. was delivered without prenatal complications. Ex. 2 at 13-14. On April 12, 2013, K.W. was seen for his two-week well exam. Ex. 5 at 18. K.W. was noted to be a "well baby" with "normal growth and development." *Id.* His only issue was a periodic cough. *Id.* at 20. On April 15, 2013, K.W. was seen for his newborn audiology exam. Ex. 8 at 1. He failed the newborn hearing screening on the right side once, but passed on a second try. Ex. 9 at 1. His ears were otherwise found to be functionally normal. Ex. 8 at 1.

On April 25, 2013, K.W. was seen for his one-month well exam. Ex. 5 at 22. K.W. was noted to be a "well baby" with normal growth and development. *Id.* K.W. continued to have a persistent cough, but his pediatrician was unconcerned. *Id.*

On April 30, 2013, K.W. was diagnosed with a case of baby acne. Ex. 5 at 24. Dr. Eke explained that the rash was benign. *Id.*

On May 28, 2013, K.W. presented for his two-month well exam. Ex. 5 at 25-26. At this appointment, he was again found to be a healthy child. *Id.* at 26. He received his Prevnar, Pediarix, Hib, and Rotavirus vaccinations at this appointment. *Id.* On June 12, 2013, Petitioners brought K.W. to the doctor, as he was "coughing, sleeping a lot, and had a runny nose." Ex. 5 at 27. K.W. was diagnosed with a viral illness. *Id.* Doctors ordered lab tests which determined K.W.'s platelet count was 619,000. *Id.* at 5. The records note that this platelet level was high. *Id.* at 18.

On July 31, 2013, K.W. presented to Dr. Eke for his four-month well exam. Ex. 5 at 28-29. He was diagnosed with a common cold, but was otherwise healthy. *Id.* at 29. He was given Pentacel, Prevnar, and Rotovirus vaccines at this appointment. *Id.*

On August 7, 2013, Ms. Walls took K.W. to the doctor. Ex. 5 at 30. He presented with diarrhea which the doctor recommended treating with Pedialyte. *Id.* at 31.

On September 8, 2013, K.W. was diagnosed with a cold during a pediatric visit. Ex. 4 at 98. On September 9, 2013, Petitioners brought K.W. to the doctor with a cough. *Id.* at 32. He had no fever and his diagnosis was changed to an upper respiratory infection ("URI"). *Id.* K.W. was released and Petitioners were given instructions to call if K.W.'s health worsened. *Id.* On September 12, 2013, K.W. visited the emergency room at Berkeley Medical Center for the URI. Ex. 4 at 98-99.

On October 1, 2013, K.W. presented for his six-month well exam. Ex. 5 at 33-34. The doctor noted that K.W. was a "well baby." *Id.* at 34. K.W. received his Pediarix, Prevnar, Hib, and flu vaccinations at this visit. *Id.* K.W. received another flu vaccine on November 12, 2013. *Id.* at 51.

On November 28, 2013, K.W. presented to the Berkeley Medical Center emergency room again, but with a fever of 103.6º that had lasted for four days, beginning on November 24, 2013. Ex. 4 at 108-12. He was diagnosed with an acute URI. *Id.* at 108. The doctor prescribed K.W. antibiotics and released him home. *Id.* at 112.

On January 16, 2014, K.W. was diagnosed with a common cold. Ex. 5 at 50. On February 4, 2014, K.W. presented for his nine-month well exam. *Id.* at 48. The doctor was concerned that K.W. was not gaining weight properly. *Id.* at 49. In addition, the records note that K.W. was exposed to secondhand, or "passive" smoke. *Id.* at 49. K.W.'s hemoglobin was measured at 11.3 at this visit. *Id.* He was ordered to return in one month for a weight check. *Id.* at 47. At that weight check, K.W. was underweight but otherwise healthy. *Id.*

On March 7, 2014, K.W. saw Dr. Eke at City Pediatrics for what was diagnosed as nonsuppurative otitis media (a noninflammatory ear infection) and the common cold. Ex. 5 at 45. K.W. returned on March 10, 2014 for feeding difficulties, a viral illness, and ear infection. *Id.* at 43. Dr. Eke ordered a blood platelet test that was within normal range at 239.[5] *Id.* at 3, 43, 63. At a follow-up visit on March 18, 2014, K.W.'s symptoms had largely dissipated, though he was coughing. *Id.* at 42. On May 2, 2014, K.W. was once again seen at urgent care for ear problems. Ex. 6 at 22. He was diagnosed with persistent fluid behind the ear membrane, but no ear infection. *Id.*

On May 21, 2014, K.W. switched primary care providers. Ex. 6 at 19-21. The records note that K.W.'s diarrhea was likely caused by his grandmother feeding him juice every day. *Id.* The doctor's notes also indicate that K.W. had a history of anemia, from the age of six months until he was nine months old. *Id.* The notes state that the anemia had resolved. *Id.* Petitioners were also reassured that the number of illnesses suffered by K.W. up until this point in his life was "normal." *Id.* at 20.

[5] Platelet count was reduced to K/uL, which is equivalent to 239,000 platelets per microliter of blood.

K.W. subsequently went to urgent care at Berkeley Family Medical Associates on June 3, 2014 for a cough, fever, and an ear infection. Ex. 6 at 16-17. K.W. was prescribed antibiotics and sent home. *Id.* On June 9, 2014, K.W. returned complaining about ear pulling and was encouraged to take Children's Zyrtec and continue taking the prescribed antibiotics. *Id.* at 13-15. On June 13, 2014, K.W. presented to an audiologist who stated that K.W. had "no evidence of acute otitis media or effusion." Ex. 9 at 1.

On July 16, 2014, K.W. went to his 15-month well exam, where he was assessed to be a well child. Ex. 6 at 10-12. K.W.'s temperature was recorded as 99.6º. *Id.* at 11. K.W. received the DTaP, Hib, Hep B, and Prevnar 13 vaccines on the same day. *Id.* at 10-11.

**B. Post-Vaccination History**

On July 30, 2014, K.W. was seen in urgent care by Dr. James Payne at Berkeley Family Medical Associates. Ex. 6 at 7. Dr. Payne noted that:

> Parents report pt has had several new bruises over the last 6 days with no known trauma. Parents reports [sic] son recently started walking and frequently has bruises on his legs and arms when he bumps into things or falls, but have noticed increased bruising which they feel may be abnormal and are concerned. They report pt is acting normally and report he feels warm today but they deny and [sic] known recent illness. Parents report that pt is not in daycare and his only babysitter is his grandmother. They deny any concerns for abuse. Parents deny any other current problems or concerns.

*Id.* at 8. Dr. Payne recommended that if K.W. developed a fever of 100.4º or greater or if there was any obvious bleeding to go to the emergency room. *Id.* at 9. Dr. Payne's notes further stated that Petitioners reported:

> No ear pain, no ear discharge, no hearing loss, no sinus pressure, no drooling, no facial swelling, no congestion, no sore throat, no hoarseness, and no mouth lesions. (S)he reports no chest pain and normal heart rate. (S)he reports no lumps, no tenderness, and no discharge. (S)he reports no cough, no wheezing, no chest tightness, no pain with respiration, and normal respiration. (S)he reports no difficulty swallowing, no abdominal pain, no nausea, no vomiting, no diarrhea, no constipation, no blood in stools, and no mucous in stool. (S)he reports no discharge, no blood in urine, no increase in frequency of urination, no swelling, no redness, no itching, and no masses. (S)he reports no soft tissue swelling, no joint swelling, no myalgia, moves all extremities well, no previous injuries, and no trauma. (S)he reports no weakness, no burning, no shooting pain, no headache, no dizziness, and no loss of consciousness. (S)he reports normal drinking. (S)he reports no sneezing and no runny nose."

*Id.* at 8.

On July 31, 2014, Ms. Walls brought K.W. to the Berkeley Medical Center emergency

room, where he was seen by Dr. Daryl La Russo. Ex. 4 at 150. Dr. La Russo noted that:

> mother states that she began to notice "a lot of bruising" this past Friday. The patient has had a fever on [sic] yesterday, and he has had green "pudding soft" diarrhea for the past 2-3 days.… The parents were informed to bring the patient into the ED for a low platelet count from the labs that were drawn yesterday…. He did have cold symptoms 2 weeks ago.

*Id.* K.W.'s platelet count was 29 K/uL. *Id.* at 152. K.W. was diagnosed with acute idiopathic thrombocytopenia and was discharged. He was scheduled to follow-up at Children's National Medical Center the next day. *Id.* at 153.

On August 1, 2014, K.W. was seen by Dr. Lori Luchtman-Jones at Children's National Medical Center ("Children's National") in Washington, DC. Ex. 10 at 34. Dr. Luchtman-Jones noted that K.W. "presented to our clinic with thrombocytopenia with bruises and petechiae." *Id.* She further noted that: "3 [weeks] – after 7/4 – cough, mind fever, runny nose: 1.5 weeks." Ex. 10 at 2. The record further indicates that K.W. had "loose stools" for the past three days. *Id.* Dr. Luchman-Jones noted that there was a history of anemia on K.W.'s mother side, and also noted (incorrectly) that he received his vaccinations on July 15, 2014. *Id.*

A complete blood count (CBC) measured K.W.'s platelet count at 26,000. *Id.* Dr. Luchtman-Jones informed Petitioners that because K.W.'s platelets were above 20,000 and stable, he did not need to receive treatment, but continual testing would need to be done to monitor his ITP. *Id.* Further, if his platelets fell below 20,000, he would need to be admitted to a hospital. *Id.*

Over the next ten months, K.W. continued to have his platelet count checked and the results are as follows:

| **Date of Test** | **Platelet Count** | **Exhibit** |
|---|---|---|
| 8/4/2014 | 53,000 | Ex. 4 at 169 |
| 8/11/2014 | 55,000 | Ex. 4 at 181 |
| 8/18/2014 | 66,000 | Ex. 5 at 2 |
| 8/25/2014 | 84,000 | Ex. 4 at 206 |
| 9/8/2014 | 44,000 | Ex. 4 at 214 |
| 9/17/2014 | 48,000 | Ex. 4 at 228 |
| 10/16/2014 | 73,000 | Ex. 4 at 237 |
| 11/6/2014 | 68,000 | Ex. 4 at 245 |
| 12/2/2014 | 129,000 | Ex. 4 at 255 |

| Date of Test | Platelet Count | Exhibit |
|---|---|---|
| 1/5/2015 | 537,000 | Ex. 4 at 264 |
| 3/2/2015 | 61,000 | Ex. 4 at 272 |
| 3/23/2015 | 97,000 | Ex. 4 at 286 |
| 4/16/2015 | 148,000 | Ex. 4 at 296 |
| 5/19/2015 | 179,000 | Ex. 4 at 306 |
| 5/31/2015 | 178,000 | Ex. 4 at 335 |
| 6/15/2015 | 486,000 | Ex. 4 at 348 |

On May 20, 2015, Dr. Christine Higham of Children's National discussed with Ms. Walls via telephone that K.W.'s platelet count was stable. Ex. 10 at 23. The records note that K.W. was "doing great and has had no symptoms of thrombocytopenia since the beginning of March." *Id.* Dr. Higham informed Ms. Walls that K.W. no longer needed routine CBCs but discussed the signs of thrombocytopenia and if there were such signs to obtain a CBC. *Id.*

Petitioners did not file subsequent medical records pertinent to this ruling.

## III. Petitioner's Affidavit

Petitioner Ashley Walls submitted an affidavit on May 10, 2016. Ex. 14. Ms. Walls stated that K.W. was a "healthy child" prior to his 15-month vaccinations. *Id.* at ¶ 1. Ms. Walls indicated that K.W. did "not have any major illnesses, including diaper rash, colic, croup, or strep." *Id.* "He did have a couple [of] ear infections for which he took prescription medicine, but they resolved within ten days." *Id.*

At the end of June 2014, "K.W. had a cold that lasted about a week." *Id.* at ¶ 2. "His symptoms were a runny nose, congestion, and mild fever, but he did not require medical attention. That quickly cleared by the end of that month." *Id.*

On July 16, 2014, K.W. was taken to his pediatrician for his 15-month wellness visit. *Id.* at ¶ 3. His temperature was "slightly elevated" but "the doctor said that otherwise he was doing well for his age." *Id.* He received the DTaP, Hep B, Hib and pneumonia vaccines at this visit. *Id.*

"A few days" after K.W.'s July 16, 2014 wellness visit, Ms. Walls and her mother "began to notice weird bruises in different places on K.W." *Id.* at ¶ 4. Ms. Walls believed that this may have been due to anemia and "that maybe his iron was low, especially because [Petitioner is] also anemic." *Id.*

On July 30, 2014, Ms. Walls brought K.W. to the doctor's office to have the bruising examined. *Id.* at ¶ 5. The doctor ordered bloodwork. *Id.* On July 31, 2014, bloodwork was

performed on K.W. *Id.* at ¶ 6. Thereafter, Petitioners received a call from the hospital "stating that K.W.'s platelets were dangerously low, and that we needed to get him to the ER." *Id.* At the emergency room, it was explained to Petitioners that K.W. was diagnosed with ITP. *Id.*

On August 1, 2014, Petitioners took K.W. to Children's Hospital, where more bloodwork was ordered. *Id.* at ¶ 7. K.W. was required to "have bloodwork done once a week to monitor his platelet levels." *Id.* It was recommended that K.W. not 'rough house' "until his platelet levels came up to a safer range." *Id.*

In January 2015, K.W.'s platelet levels were measured at 537,000. *Id.* at ¶ 9. It was explained to Petitioners that K.W. had not exhibited symptoms of ITP "for some time." *Id.* Accordingly, the routine bloodwork would stop until signs of bruising were seen again. *Id.* K.W. has not received a vaccine since his ITP diagnosis. *Id.* at 12.

## IV. Expert Opinions

### A. Petitioners' Expert: Dr. Edwin N. Forman

Petitioners filed three reports from Dr. Edwin N. Forman, M.D. *See* Exs. 16 (hereinafter "First Forman Rep."), 18 (hereinafter "Second Forman Rep."), 20 (hereinafter "Third Forman Rep."). He also filed comments to the Cines II article, ECF No. 73 (hereinafter "Fourth Forman Rep.").

#### 1. Qualifications

Dr. Forman received his medical degree from the University of Pennsylvania School of Medicine. *See* Ex. 17 ("Forman CV"). Following completion of his medical degree, Dr. Forman completed a residency at the Johns Hopkins Hospital in Pediatrics and a fellowship at the United States Public Health Service, University of Illinois Research and Educational Hospital in Pediatric Hematology and Oncology. Forman CV at 3. Dr. Forman has held numerous hospital and academic positions, including a teaching position at Brown University for 41 years. Brown University has established a chair in honor and recognition of Dr. Forman's work with pediatric cancer patients, as well as his work in biomedical ethics. *Id.* at 4. He is presently an attending physician at the Mount Sinai Hospital and Professor of Pediatrics at Icahn School of Medicine at Mount Sinai. *See id.* at 1-3.

Dr. Forman is board certified in Pediatrics and Pediatric Hematology/Oncology. Forman CV at 3-4. He is a member of the American Academy of Pediatrics, and the American Board of Pediatrics Committee on Hematology-Oncology, which writes the certifying exam. *Id.* at 6. Dr. Forman conducted research for nearly 30 years and has published over 80 articles covering pediatric hematology and oncology, including several articles on thrombocytopenia purpura. *See id.* at 14-22.

#### 2. Dr. Forman's Opinion

Dr. Forman opined that K.W. developed ITP from one or more of the vaccines he received on July 16, 2014. First Forman Rep. at 2-3.

Dr. Forman cites to articles that show evidence that ITP occurs at a higher rate following certain immunizations. *See* First Forman Rep. at 2; *see also* Didier Neau, et al., *Immune Thrombocytopenic Purpura After recombinant Hepatitis B vaccine: Retrospective Study of Seven Cases*, 30 SCANDINAVIAN J. INFECTIOUS DISEASES 115-18 (1998) (hereinafter "Neau") (filed as Ex. 16, Tab J); Francesca Ronchi, et al., *Thrombocytopenia Purpura as Adverse Reaction to Recombinant Hepatitis B Vaccine*., 78 ARCHIVES OF DISEASE IN CHILDHOOD, 273-74 (1998) (hereinafter "Ronchi") (filed as Ex. 16, Tab K); Hector Neuvo, et al., *Thrombocytopenia Purpura After Hepatitis B Vaccine: Case Report and Review of the Literature*, 23 PEDIATRIC INFECTIOUS DISEASE J., 183-84 (hereinafter "Neuvo") (filed as Ex. 16, Tab L); Pascale Poullin and B. Gabriel, *Thrombocytopenic Purpura After Recombinant Hepatitis B Vaccine*, 344 LANCET 1293 (1994) (hereinafter "Poulin") (filed as Ex. 16, Tab M); Esteban Martinez and Pere Domingo*, Evan's Syndrome Triggered by Recombinant Hepatitis B Vaccine*, 15 CLINICAL INFECTIOUS DISEASES 1051 (Dec. 1992) (hereinafter "Martinez") (filed as Ex. 16, Tab N); Paul Finielz, et al. *Systemic Lupus Erythematosus and Thrombocytopenic Purpura in Two Members of the Same Family Following Hepatitis B Vaccine*, 13 NEPHROLOGY DIALYSIS TRANSPLANTATION, 2420-21 (Sept. 1998) (hereinafter "Finielz") (filed as Ex. 16, Tab O); Ronald Meyboom, et al., *Thrombocytopenia Reported in Association with Hepatitis B and A Vaccines*, 345 LANCET 1638 (June 1995) (hereinafter "Meyboom") (filed as Ex. 16, Tab P).

Dr. Forman also references case reports regarding ITP and the Hib, DPT or Tetanus, and Prevnar vaccines. *See* Institute of Medicine, Vaccine Safety Committee ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY, Kathleen R. Stratton, Cynthia J. Howe, and Richard B. Johnston, Jr., eds., 236-263 (1994) (hereinafter "Vaccine Safety Committee Report") (filed as Ex. 16, Tab C); Luc Mortelmans, et al., *Thrombocytopenia After Tetanus Vaccination*., 16 EUR. J. EMERGENCY MED. 345-46 (Dec. 2009) (hereinafter "Mortelmans") (filed as Ex. 16, Tab E); Laxman Singh Arya, et al., *Thrombocytopenic Purpura Following DPT Vaccination*, 10 J. PEDIATRIC HEMATOLOGY AND ONCOLOGY 381-83 (1993) (hereinafter "Arya") (filed as Ex. 16, Tab F); Antonio Torrelo, et al., *Deep Morphea After Vaccination in Two Young Children*, 23 PEDIATRIC DERMATOLOGY 484-87 (Sept. – Oct. 2006), (hereinafter "Torrelo Case Study") (filed as Ex. 16, Tab G); Francesco Drago et al., *Generalized Morphea after Anti-Tetanus Vaccination*, 23 CLINICAL AND EXPERIMENTAL DERMATOLOGY 142 (1998) (hereinafter "Drago") (filed as Ex. 16, Tab H); Sushil Gupta and Daniel C. Brennan, *Pneumococcal 13-Valent Conjugate Vaccine (Prevnar 13) – Associate Immune Thrombocytopenia Purpura in a Renal Transplant Recipient*, 48 TRANSPLANT PROCEDURE 262-64 (Jan. 2016) (hereinafter "Gupta") (filed as Ex. 16, Tab I).

Dr. Forman proposes a theory of molecular mimicry to explain K.W.'s ITP:

> The mechanism by which an infection or a vaccine can cause ITP is not definitely known, however it is understood that the immune system is stimulated to make antibodies against one's own platelets. An infection by a live organism and a vaccine to prevent infection by that organism share similar antigens. Molecular mimicry involves cross-reaction to self-antigens, thereby inducing autoimmunity.

First Forman Rep. at 2-3. According to Dr. Forman, the Cines II article supports molecular mimicry as a causal theory. *See* Fourth Forman Rep.; Cines II at 6518.

Dr. Forman states that ITP generally develops one to four weeks after a viral infection or immunization, with peak incidence between one and two weeks. First Forman Rep. at 3. K.W.'s bruising began on July 25, 2014, nine days after his vaccinations on July 16, 2014, which Dr. Forman states is consistent with the appropriate time interval for the development of ITP. *Id.* Dr. Forman also notes that the peak incidence of ITP "occurs between one and four years of age." *Id.* K.W. was approximately 16 months old when he was diagnosed with ITP. Ex. 1.

In response to Respondent's expert report from Dr. Gill, Dr. Forman states that K.W.'s fever, runny nose, and congestion at the end of June 2014 was unlikely to have caused K.W.'s ITP. Second Forman Rep. at 1. Dr. Forman states the contemporaneous medical records indicate that K.W. had no recent illnesses when he was admitted for bruising. *Id.*; *see also* Ex. 6 at 9.

Dr. Forman also states that K.W.'s prior viral illness during the end of June 2014 was not the most probable cause of K.W.'s ITP diagnosis. *Id.* Dr. Forman specifically states that

> even if there had been a prior viral illness, it remains my opinion that one or more of the four vaccines that he received are likely to have been the principal cause of his ITP. The peak incidence of ITP after an antigenic stimulus-viral or immunization-usually occurs within 1 to 4 weeks with a peak incidence at 1 to 2 weeks. [K.W.] experienced the onset of symptoms of his ITP approximately 1 to 2 weeks following his vaccinations. Therefore, it is possible that a prior viral infection may have had a contributing impact by priming the immune system, but if not for the vaccinations, [K.W.'s] ITP would not have occurred.

Second Forman Rep. at 1.

Dr. Forman's third report was in response to Dr. John Strouse. Dr. Forman noted that an emergency room record mentioned K.W. had a cold two weeks prior to the onset of bruising but this notation is not supported by the July 16, 2014 well-child visit or Ms. Walls' affidavit. Third Forman Rep. at 1. Dr. Forman also included two case studies that purported to show the development of ITP after specific vaccines, including those received by K.W. *Id.* Dr. Forman in particular cited an article also cited by Respondent's expert Dr. Strouse which said that "[b]ecause vaccines are designed to induce an immune response that mimics natural infection to produce immunological protection, it is theoretically possible that vaccines besides MMR could trigger ITP." *Id.* at 2 (*citing* Sean T. O'Leary, et al., *The Risk of Immune Thrombocytopenic Purpura after Vaccination in Children and Adolescents*, 129 J. PEDIATRICS 248-55 (2012) (hereinafter "O'Leary") (double-filed as Ex. B3 and Ex. F1).

**B. Respondent's Expert: Dr. Joan Gill**

Respondent filed a report from Dr. Joan C. Gill. Ex. A (hereinafter "Gill Rep."). Due to her health, Dr. Gill had to withdraw as an expert in this case. She sadly passed away during the

pendency of this matter. However, her expert report remains a part of the record. Dr. Gill's CV was filed as Exhibit C (hereinafter "Gill CV").

1. Qualifications

Dr. Gill received her medical degree from the Medical College of Wisconsin. Gill CV at 1. She completed her residency in pediatrics at the Milwaukee Children's Hospital. *Id.* Dr. Gill completed a pediatric hematology-oncology fellowship at the Medical College of Wisconsin and Blood Center of Southeastern Wisconsin. *Id.* Dr. Gill taught at the Medical College of Wisconsin for nearly 40 years and served as director at numerous institutions but notably was the medical director of the Hemophilia and Bleeding Disorders Center at the Children's Hospital of Wisconsin for 15 years. *Id.* at 2-3. Dr. Gill was board certified in pediatrics and pediatric hematology/oncology. *Id.* at 4. Dr. Gill had conducted research related to hematology and hemophilia since 1982 and had published hundreds of pieces of literature. *Id.* at 11-45.

2. Dr. Gill's Opinion

In Dr. Gill's report, she opined that K.W.'s infection in June 2014 was within the usual time course for post-infectious ITP. Gill Rep. at 3. Dr. Gill stated that K.W.'s vaccinations would not be within a typical time course of a vaccine reaction. *Id.* K.W. had received these vaccines three times prior. The production of antibodies in response to vaccines is generally 10-14 days at first exposure but is reduced to 24-48 hours in the case of multiple exposures to a vaccine. *Id.*; *see also* David Baxter, *Active and Passive Immunity, Vaccine Types, Excipients, and Licensing*, 57 OCCUPATIONAL MEDICINE 552-56 (2007) (hereinafter "Baxter") (filed as Exhibit B1). Dr. Gill additionally stated that the development of ITP after receiving booster doses is "very rare." Gill Rep. at 3.

Dr. Gill cited a cohort study of 1.8 million children from 6 weeks to 17 years of age for the presence of ITP. Gill Rep. at 3; *see also* O'Leary at 3. The study found that there was "no significantly elevated risk of ITP after any vaccine in early childhood other than MMR in the 12 – 19-month age group." Gill Rep. at 3-4; *see generally* O'Leary Study. Thus, it was Dr. Gill's opinion that K.W.'s respiratory illness in June 2014, "the most common cause of acute ITP," was what led to K.W.'s development of ITP. Gill Rep. at 4.

**C. Respondent's Expert: Dr. John Strouse**

Respondent filed three reports from Dr. John J. Strouse, M.D., Ph.D. Ex. D (hereinafter "First Strouse Rep."), Ex. G (hereinafter "Second Strouse Rep."), and Ex. H (hereinafter "Third Strouse Rep."). Dr. Strouse's CV was filed as Exhibit E (hereinafter "Strouse CV").

1. Qualifications

Dr. Strouse received his medical degree from the Johns Hopkins University School of Medicine in 1996. Strouse CV at 1. Dr. Strouse completed his residency at the University of Rochester and fellowships at the National Institutes of Health in hematology and pediatric oncology and a fellowship at Johns Hopkins University for pediatric hematology/oncology. *Id.* at

2. Dr. Strouse held academic positions at Johns Hopkins but is currently an Associate Professor of Medicine and Pediatrics at Duke University. *Id.* Dr. Strouse is board certified in pediatrics, hematology, and pediatric hematology/oncology. *Id.* at 1.

In addition to his academic and hospital appointments, Dr. Strouse has published over 80 articles covering pediatric hematology and oncology. Strouse CV at 2-8. Dr. Strouse is on the editorial boards for four hematological organizations and journals and has peer-reviewed publications for various journals such as Pediatrics, Journal of the American Medical Association, Stroke, and American Journal of Hematology. *Id.* at 12.

2. Dr. Strouse's Opinion

In Dr. Strouse's first report, he finds:

> the time of onset [of ITP] to be most consistent with recent viral infection in late June 2014 as immune mediated thrombocytopenia associated with the 4th doses of vaccine would be most likely to have developed in a shorter period of time because of the booster effect of the multiple doses of vaccine.

First Strouse Rep. at 2. Dr. Strouse points out that certain viral infections have been strongly associated with ITP, such as HIV, hepatitis C, measles, rubella, Epstein-Barr, and varicella.[6] *Id.* The viruses for which K.W. developed immunity through his vaccines have not been associated with ITP, except for Hepatitis B in adults, but not for children. *Id.*

Dr. Strouse also cites to the O'Leary Study as evidence that it is unlikely K.W. developed ITP from his vaccinations. First Strouse Rep. at 2-3.

In Dr. Strouse's second report, he refutes Dr. Forman's claim that K.W.'s development of ITP was not secondary to any potential virus illness alone. Second Strouse Rep. at 1. He states that K.W.'s development of ITP was within the 1 to 4 weeks after onset of a viral illness as typically seen in pediatric ITP. *Id.* The relationship between viral infections and ITP in children is clear, however "the best available evidence does not support an association between any of the four vaccines [K.W.] received." *Id.*

Dr. Strouse filed his third report in order to comment on the Cines II article. In this report, Dr. Strouse reiterated that the relationship between antecedent viral infection and ITP has been demonstrated through epidemiological study. Third Strouse Rep. at 1. He further stated that the reports of ITP after DTaP, pneumococcal conjugate, and Hep B vaccines "are to be expected by chance alone." *Id.*

## V. Applicable Law

### A. Petitioner's Overall Burden in Vaccine Program Cases

[6] There is no evidence in the record that K.W. had any of these viral infections.

Under the Vaccine Act, petitioners may prevail in one of two ways. First, petitioners may demonstrate that a vaccinee suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a vaccinee may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, petitioners must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, petitioners must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners establish by preponderant evidence that the vaccinations received caused the injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, petitioners' theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is plausible or possible does not satisfy petitioners' burden. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered

by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015), *rev'd on other grounds*, 844 F.3d 1263 (2017)

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

### B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/71 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *mot. for review denied* (Fed. Cl. Feb. 11, 2019), *rev'd on other grounds*, No. 2019-1753, 2020 U.S. App. Lexis 10904 (Fed. Cir. April 7, 2020); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell*

*v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate

persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

### D. Consideration of Medical Literature

Although this ruling discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

## VI. Analysis

Because Petitioners do not allege an injury listed on the Vaccine Injury Table, Petitioners' claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioners must prove by preponderant evidence that K.W. suffered an injury and that this injury was caused by the vaccinations at issue. *See Capizzano*, 440 F.3d at 1320.

### A. ITP Generally

ITP is an autoimmune disorder characterized by a low platelet count and mucocutaneous bleeding. Douglas B. Cines and Victor S. Blanchette, *Immune Thrombocytopenia Purpura*, 346 NEW ENGLAND J. MED. 995-1008 (2002) (hereinafter "Cines I") (filed as Exhibit B2). ITP is classified as primary or as secondary to an underlying disorder and can be further classified into

either acute or chronic ITP. *Id.* at 1008. In more than 70% of children with ITP, the illness resolves within six months, irrespective of whether they receive therapy. *Id.*

The exact cause of ITP is unknown. Dr. Forman stated that "the diagnosis of ITP is made primarily on clinical grounds and the exclusion of other conditions." First Forman Rep. at 2. This is supported by Respondent's medical literature. *See* Deirdra R. Terrell, et al*., The Incidence of Immune Thrombocytopenia Purpura in Children and Adults: A Critical Review of Published Reports*, 85 AM. J. HEMATOLOGY 174-80 (2010) (hereinafter "Terrell") (filed as Exhibit B6).

**B. K.W.'s ITP Diagnosis**

Both Petitioners and Respondent agree that K.W. meets the diagnostic criteria for ITP. *See* First Forman Rep. at 1; Gill Rep. at 1. K.W.'s medical records are clear that he was diagnosed with ITP on July 31, 2014. Ex. 4 at 149-50; Ex. 10 at 1. The medical records and expert reports are also in agreement that the onset of K.W.'s bruising was on July 25, 2014.[7] *See* First Strouse Rep. at 2, First Forman Rep. at 1, Ex. 4 at 149-50.

**C. Petitioners Have Carried Their Burden of Proof**

1. *Althen* Prong 1

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Human Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

a. *Molecular Mimicry*

Here, Petitioners have advanced a theory of molecular mimicry to explain how K.W. developed ITP after his vaccinations. Dr. Forman states that molecular mimicry "involves cross-reaction to self-antigens, thereby inducing autoimmunity." First Forman Rep. at 3. Several of the medical articles filed in this case provide support for this theory in the context of developing ITP. The Gupta article states that "[a]ntibodies formed during viral or bacterial infections may … cross-react with normal platelet antigens (a form of molecular mimicry)." Gupta at 4. The Cines II

[7] I note that the problem section of the July 16, 2014 medical record states "Multiple bruising". Ex. 6 at 10. There is no further mention or discussion of bruising in this record. In fact, the physical exam of K.W.'s skin indicates "Color and Pigmentation: no cyanosis, rash, or lesions." *Id.* at 12. Insofar as this medical record could be interpreted to mean that K.W. experienced bruising related to his ITP on July 16, 2014, it is inconsistent with the other medical records in this case, which all indicate that K.W.'s abnormal bruising began on July 25, 2014. *See* Ex. 6 at 8 (medical record from July 30, 2014 indicating bruising over the past six days); Ex. 4 at 150 (medical record from July 31, 2014 indicating mother noticed a lot of bruising this past Friday); Ex. 10 at 2 (medical record from August 1, 2014 indicating "last Friday--bruises--legs, knees, ribs, back"). I further note that none of the experts in this case mentioned this annotation, and all three of them have indicated that onset of bruising began on July 25, 2014. For all these reasons, I find the preponderant weight of the evidence establishes that K.W.'s bruising began on July 25, 2014.

article states that some ITP cases "are associated with antiviral antibodies that cross-react with platelet GPIIb/IIIa." Cines II at 6518.

Molecular mimicry is a well-established theory in the Vaccine Program and has been persuasively linked to immune-mediated conditions, to include ITP. *Johnson v. Sec'y of Health & Human Servs.*, No. 14–113V, 2017 WL 772534 (Fed. Cl. Spec. Mstr. Jan. 6, 2017) (finding petitioner presented sufficient evidence to conclude the HPV vaccine can cause ITP); *Ebenstein v. Sec'y of Health & Human Servs.*, No. 06–573V, 2010 WL 5113185, at *21 (Fed. Cl. Spec. Mstr. Sept. 1, 2010) (accepting that molecular mimicry links the MMR vaccine and ITP).

b. *Vaccination and ITP*

In addition to providing support for their theory of molecular mimicry, the record contains evidence linking vaccination in general to the development of ITP, a concept that also appears to be well supported in the literature. The Sauvé article, which examined postvaccination ITP in Canada stated, "[t]here is an increasing evidence to support a link between vaccinations and thrombocytopenia, which occurs after approximately 1 in 25,000 to 1 in 40,000 doses of measles-mumps-rubella (MMR) vaccine and less frequently after other vaccines." Laura J. Sauvé et al., *Postvaccination Thrombocytopenia in Canada*, 29 PEDIATRIC INFECTIOUS DISEASES J. 559-61 (2010) (filed as Ex. B5). A medical textbook on pediatric hematology also supports a link between vaccinations and ITP, stating, "[o]ften a viral infection or vaccination precedes the onset of acute ITP." Nathan and Oski's, HEMATOLOGY OF INFANTS AND CHILDHOOD, 8th ed., Philadelphia, PA 2015 at 1079-80 (filed as Ex. 16, Tab A) (hereinafter "Nathan and Oskis").

Based on the above, it is clear that there is medical literature which supports a link between vaccination generally and ITP. Although the precise biological mechanism is unknown, Petitioners' theory of molecular mimicry is biologically probable.

c. *DTaP, Hib, Hep B, and PCV Vaccinations*

Although the literature articulates a strong link between the MMR vaccine and ITP, there is evidence that the vaccines K.W. received can cause ITP as well. The Cines II article states, "Acute ITP occurs after vaccinations against several infectious agents. Best studied is measles-mumps-rubella (MMR) vaccination, but there is reasonable documentation for acute thrombocytopenia developing after vaccination against pneumococcus, *Haemophilus influenzae* B, hepatitis B virus, and varicella-zoster virus (VZV)." Cines II at 6513. While the term "reasonable documentation" is not defined, it suggests the theory that acute ITP developing after several non-MMR vaccines possesses an indicia of reliability.

Respondent cites the O'Leary article in support of their argument that the vaccines K.W. received do not cause ITP. This article discussed a study of a cohort of 1.8 million children in ages ranging from six weeks to 17 years. This study found no elevated risk of ITP in early childhood except among children in the 12-19 month age group who received the MMR vaccine. O'Leary at 2. O'Leary found, however, that the risk of ITP after Hep A, varicella, and tetanus-diphtheria-acellular pertussis vaccine (Tdap) was significantly elevated in three discrete age categories (involving older children). *Id.* at 5. As the authors note, "it is … unclear why these

vaccines would trigger ITP in older age groups but not in younger ones." *Id.* at 6. The article also states that "[b]ecause vaccines are designed to induce an immune response that mimics natural infection to produce immunologic protection, it is theoretically possible that vaccines besides MMR could trigger ITP." O'Leary at 2. Although a statement of theoretical possibility does not, by itself, establish that vaccines other than MMR can cause ITP, it does, when combined with the Cines II article and case reports cited by Petitioners, provide some support for Petitioners' causal theory.

Petitioners also submitted case reports demonstrating a link between the vaccines that K.W. received and the onset of ITP. *See, e.g.*, Gupta at 1 ("Immune thrombocytopenia (ITP) is a rare side effect associated with administration of [the PCV13] vaccine"); Ronchi at 1 ("The recombinant hepatitis B vaccine, presently used worldwide, is highly immunogenic but is generally well tolerated. Serious adverse reactions such as anaphylaxis and polyradiculoneuritis, demyelination of the central nervous system, liver dysfunction and DNA antibodies, or Evan's syndrome (autoimmunehaemolytic anaemia and thrombocytopenia) are reported very rarely.") (omitting internal citations); Nuevo at 1 ("ITP may be an adverse event after several vaccines."); Meyboom at 1 ("data reported to the WHO Collaborating Centre suggest that hepatitis B and perhaps also hepatitis A vaccination may in rare cases induce thrombocytopenia"); Arya at 3 ("DPT immunization may be a rare cause of immune-mediated thrombocytopenia and…the low platelet count can persist for several months"). While case reports do not represent the most persuasive evidence of causation, they do have some evidentiary value. *See, e.g., Campbell*, 97 Fed. Cl. at 668 ("the fact that case reports can by their nature only present an indicia of causation does not deprive them of all evidentiary weight").

Respondent cited to a number of epidemiologic studies in an effort to demonstrate that no vaccine other than MMR is credibly linked to ITP. Epidemiologic evidence is relevant with respect to *Althen* prong 1. *See, e.g., D'Tiole v. Sec'y of Health & Human Servs.,* 2016 U.S. Claims LEXIS 2003 (Fed. Cl. Spec. Mstr. Nov. 28, 2016), *aff'd*, 132 Fed. Cl. 421 (2017); *Blackburn v. Sec'y of Health & Human Servs.*, No. 10–410V, 2015 WL 425935, at *28–30 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). However, this type of evidence is not required in order for a petitioner to establish that a vaccine can cause an injury. A vaccine injury is a rare event that cannot be disproved because a vaccinee did not experience a response consistent with that of the general population. *See Harris v. Sec'y of Health & Human Servs.*, No. 10–322V, 2014 WL 3159377, at *11 (Fed. Cl. Spec. Mstr. June 10, 2014) (finding that epidemiologic studies cannot absolutely refute causal connections, because it is possible that a larger study could always detect an increased risk), *mot. for review dismissed*, 2015 U.S. App. LEXIS 7921 (Fed. Cir. 2015).

d. *ITP after a Vaccine Dose Other than the Initial Dose*

One reason Respondent contends that K.W.'s vaccinations were unlikely to have caused his ITP is because K.W. received booster doses of each vaccine, and booster doses do not cause ITP. In her report, Dr. Gill stated that the development of ITP after booster doses of a vaccine is "very rare." Gill Rep. at 3. In support of this statement, she cited to a Canadian surveillance study of vaccine-related ITP "where none of the five children with a previous history of ITP had a known vaccine administration with the previous episode." *Id.* In their discussion, the authors briefly discussed a study indicating that there was no risk of ITP after a second dose of MMR vaccine.

Sauvé at 2. However, this same article also stated that "[i]t is not known how often postvaccination thrombocytopenia recurs after repeat vaccination." *Id.*

Dr. Gill also discussed the Rajante article, involving a study of 506 cases of ITP where thirty-five patients had been vaccinated within one month before diagnosis. Twenty-four patients received a first dose of MMR. "No case of thrombocytopenia in older children after a subsequent MMR doses was reported." Rajante at 2. Although these results provide some limited support for Dr. Gill's position regarding vaccine booster doses, they do not go so far as to establish that K.W. could not have developed ITP after a booster dose of a vaccine.

While there is some support for the proposition that ITP could be less likely after multiple doses of a vaccine, the value of this evidence is limited. Notably, the Vaccine Injury Table does not differentiate between the initial dose and the booster dose of MMR with respect to the ability of a petitioner who suffers from ITP to establish entitlement to an award. *See* 42 C.F.R. § 100.3(a)(V)(A). Ultimately, after evaluating this argument, I am still persuaded that vaccination, to include vaccination with a booster dose of a vaccine, can cause ITP in certain circumstances.

Based on the Petitioners' expert reports, the medical literature linking vaccination to ITP, the case reports connecting some of the vaccinations K.W. received to ITP, along with the well-reasoned decisions of other special masters finding a causal connection between vaccination and ITP, I find that Petitioners have carried their burden with respect to *Althen* prong 1.

2. *Althen* Prong 2

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong.

In his report, Dr. Forman stated that the diagnosis of ITP is "made primarily on clinical grounds and the exclusion of other conditions." First Forman Rep. at 2. Dr. Forman writes that "as there was no other condition identified or present, it is most likely that one or more of the immunizations was/were a significant, if not the only, positive causative factor for the development of ITP in K.W." *Id.*

Respondent's experts do not disagree with the diagnosis of ITP. *See generally* Gill Rep., First Strouse Rep. Instead, Respondent's experts argue that K.W.'s ITP was caused by the viral infection he suffered before the onset of his ITP. Gill Rep. at 2; First Strouse Rep. at 2. In analyzing whether Respondent's claim that K.W.'s viral illness more likely than not caused his ITP, it is necessary to determine 1) whether K.W. had a preceding viral infection, and 2) if he did, when it began.

a. *K.W.'s Viral Illness*

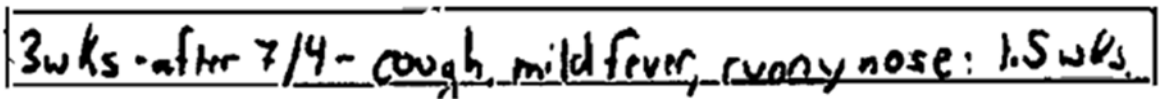
The medical records are inconsistent with regard to both of these questions -- whether K.W. suffered from a viral illness prior to the onset of his ITP and if he did, when that viral illness began.

On July 16, 2014, K.W. presented for his 15-month well-child examination. Ex. 6 at 10. PA Rhoads reported that "mother denies any complaints or concerns at this time." *Id.* at 11. The physical exam section of the record notes with respect to ear, nose, throat: "Ears: tympanic membranes pearly w/ good landmarks, pinnae well-formed, and no pits. Nose: patent and no crusts/sores. Tonsils: no erythema or exudate and not enlarged." *Id.* at 12. Regarding K.W.'s lungs the physical exam section states "Auscultation: no wheezing, rales/crackles, rhonchi, tachypnea, or retractions and clear to auscultation." *Id.* The medical record indicates that K.W.'s temperature was taken in the ear at 5:55pm and was 99.6˚.[8] *Id.* K.W. was assessed as a well child. *Id.* PA Rhoads indicated that K.W. needed routine immunizations. *Id.* No medication was prescribed. *Id.* K.W. received the vaccinations at issue on this date.

On July 30, 2014, Petitioners brought K.W. to urgent care because of unexplained bruising. Ex. 6 at 7-9. Petitioners reported that K.W. "is acting normally and report he feels warm today [July 30, 2014] but they deny an[y] known recent illness." *Id.* at 8.

On July 31, 2014, Petitioners brought K.W. to the emergency room. Ex. 4 at 150. This record states that K.W. "had cold symptoms 2 weeks ago." *Id.* This is contrary to the notation in the urgent care medical records from the previous day. *Compare with* Ex. 6 at 8.

On August 1, 2014, K.W. was seen by Dr. Luchtman-Jones at Children's National after bloodwork indicated that he had ITP. Ex. 10 at 1. The doctor's notes state "3 wks – after 7/4 – cough, mild fever, runny nose: 1.5 wks." *Id.* This is how the entry appears in the medical records:




The meaning of this notation is unclear. This note could indicate that K.W. had a cough, mild fever, and runny nose that began three weeks after July 4 and lasted for 1.5 weeks. Although that timeline places the duration of the cold past the August 1, 2014 appointment. The entry could also mean that three weeks prior to the August 1 appointment, K.W. had a cough that lasted for

[8] The Nelson Textbook on Pediatrics defines a fever as a rectal temperature ≥100.4˚. "Traditionally, body temperature fluctuates in a defined normal range … [97.9-100.2˚F] rectally, so that the highest point is reached in early evening and the lowest point is reached in the morning." NELSON TEXTBOOK ON PEDIATRICS, (21st ed. 2020) at 1386. A temperature taken in the ear and taken rectally are roughly equivalent. *See* Mayo Clinic, Infant and Toddler Health, https://www.mayoclinic.org/healthy-lifestyle/infant-and-toddler-health/in-depth/thermometer/art-20047410 (last accessed May 19, 2020). The fact that K.W.'s elevated temperature was not mentioned by any of the experts in this case leads me to conclude that it was not clinically significant.

1.5 weeks. Because the accuracy of the records is at issue, I note that this particular record also incorrectly lists the date of vaccination as July 15, 2014. Ex. 10 at 1.

On August 26, 2014, Dr. Christine Higham (also from Children's National) wrote a letter to PA Denise Rhoads, K.W.'s treating PA in West Virginia. Although the letter was dated August 26, 2014, it appears that Dr. Higham wrote the letter as if describing events from the perspective of August 1, 2014. In this letter, Dr. Higham wrote that "In addition to the fever that K.W. had yesterday, 3 weeks ago he also had a cold with a cough, mild fever and runny nose that Mom states lasted for 1-1/2 weeks." Ex. 10 at 33. Presumably, this means that the cold began three weeks prior to August 1, 2014, which was July 11, 2014. If this cold lasted for 1.5 weeks, as Dr. Higham notes, the cold would have lasted until approximately July 21 or 22, 2014. This is inconsistent with the record from K.W.'s medical appointment on July 16, 2014 where he was assessed as a well child. It is also inconsistent with the July 30 urgent care record where Petitioners denied K.W. had any recent illnesses.

Petitioner Ashley Walls discussed K.W.'s prior medical condition in her affidavit. In it, she stated, "[a]t the end of June of 2014, K.W. had a cold that lasted about a week. His symptoms were a runny nose, congestion, and mild fever, but he did not require medical attention. That quickly cleared by the end of that month." Ex. 14 at ¶ 2. This places the onset of K.W.'s illness on approximately June 23, 2014.

Respondent's expert Dr. Strouse opined that K.W.'s viral illness began on June 23, 2014. First Strouse Rep. at 1. Specifically, Dr. Strouse stated that K.W. suffered from "rhinorrhea, congestion, and mild fever lasing 1 to 1 ½ weeks that began approximately 6/23/14." *Id.* Dr. Strouse further wrote that he was "healthy at his next medical encounter 7/16/14, a well child visit…." *Id.* This assessment is consistent with some of the medical records and Ms. Walls' affidavit. *See* Ex. 14 at ¶ 3; Ex. 6 at 10.

In her report, Dr. Gill stated, "At the end of June, about 3 weeks before he developed bruising, K.W. had a runny nose, congestion and mild fever that lasted 1 – 1 ½ weeks but did not require medical attention." Gill Rep. at 2. Dr. Gill seems to selectively combine the information from Petitioner's affidavit and the Children's National medical record to arrive at the conclusion that K.W. had a cold three weeks before he developed bruising. Petitioner's affidavit indicates K.W. had a cold that lasted for one week, not one to one and one-half weeks. Further, the affidavit indicates this cold resolved by the end of June. Conceivably, based on the affidavit, K.W.'s cold could have started a few days before June 23, since it lasted one week and resolved *by* the end of June. Further, Dr. Gill's three-week calculation is not entirely precise. The only mention of a June onset of a viral infection is in Petitioner's affidavit, where Ms. Walls states that K.W. had *recovered* from his viral infection by the end of June, and that his illness had lasted about one week. Ex. 14 at ¶ 2. As discussed earlier, this places onset of the viral illness on June 23, 2014, more than four weeks before the onset of bruising.

Ultimately, I find the weight of the evidence in this case supports the fact that K.W. did have a cold that preceded his development of ITP. Although Petitioners affirmatively stated that K.W. did not have any recent known illness at the July 30, 2014 urgent care appointment (Ex. 6 at 8), several other records indicate the opposite. For example, the July 31, 2014 ER records (Ex. 4

at 150) and the August 1, 2014 Children's National Records (Ex. 10 at 1, 33) all indicate that K.W. had cold symptoms. Importantly, Petitioner's affidavit also affirms that K.W. had a runny nose, congestion and a mild fever. Ex. 14 at ¶ 2.

The medical records contradict one another regarding the date this viral illness began. Because these records are inconsistent, I find that Petitioner's affidavit provides the clearest statement regarding onset of K.W.'s cold symptoms. I will note that the symptoms Petitioner describes in her affidavit (runny nose, congestion and mild fever) are nerarly identical to the symptoms discussed in the Children's National medical records (a cold with a cough, mild fever and runny nose). Thus, Petitioner's affidavit is, in part, corroborated by the Children's National records. I find by a preponderance of the evidence that K.W.'s viral illness began on June 23, 2014.

b. *K.W.'s ITP Was More Likely Caused by One or More of his Vaccinations than by a Viral Infection*

Onset of ITP can occur following a viral illness between one to four weeks after the onset of the viral infection. *See* NELSON TEXTBOOK OF PEDIATRICS, Kliegman R.M., et al. (eds.), Saunders Elsevier (19th ed.), at 1714-15 (hereinafter "Nelson") (filed as Ex. 16, Tab B). ("In a small number of children, estimated about 1 in 20,000, 1-4 wk after exposure to a common viral infection, an autoantibody directed against the platelet surface develops with resultant sudden onset of thrombocytopenia."). Both Petitioners' and Respondent's experts agree with this finding. *See* First Forman Rep. at 3 ("It is known that ITP generally occurs between one and four weeks after a viral infection…."); Dr. Strouse stated "[t]herefore, the onset of symptoms was within the 1 to 4 weeks after the onset of the viral illness as typically seen in pediatric ITP…" Second Strouse Rep. at 1.

Even taking the outside date of this range, K.W.'s ITP does not fall within the temporal period discussed by the experts and in the literature filed in this case to have been caused by his viral illness. The onset of K.W.'s viral illness was June 23, 2014, while the onset of his ITP was July 25, 2014, 32 days later. There is not evidence in the record supporting the causality of a viral infection whose onset is more than four weeks before onset of ITP.

Conversely, K.W. developed ITP nine days after vaccination. Dr. Forman opined that it is more likely that the vaccinations caused K.W.'s ITP than the viral infection. Specifically, he stated, "The viral illness cited was about five weeks prior to the first symptoms of ITP. The vaccinations were given (July 16, 2014) about 1.5 weeks prior to the bruising, which is the *peak interval between exposure to a foreign antigen and the onset of ITP*." Second Forman Rep. at 1 (emphasis in original). While the onset of ITP occurred in close proximity to K.W.'s vaccinations, his viral infection was significantly more remote in time. I find this point to be persuasive.

Respondent's experts seem to determine that K.W. developed ITP as a result of his URI because the URI is statistically more likely to be the cause. However, statistical likelihood alone is not sufficient to demonstrate proof of causation. *See, e.g.*, *Knudsen*, 35 F.3d at 550 (rejecting an alternative cause theory based on "[t]he bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies"). In discussing

statistical evidence and proof of causation, the Court in *Hart* stated, "additional evidence adduced must show that the probabilities expressed are extendable to the facts of a given case and link the so validated statistical evidence into an otherwise plausible chain of causation." *Hart v. Sec'y of Health & Human Servs.*, 60 Fed. Cl. 598, 609 (2004). In this case, the statistical likelihood that K.W.'s viral infection caused his ITP is not extendable to the facts of this case, due, in part, to the length of time between the onset of the viral illness and the onset of K.W.'s ITP.

c. *Treater Notes*

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Human Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

The treating doctors did not opine that K.W.'s vaccinations caused his ITP. However, on October 15, 2014, when K.W. visited PA Rhoads for a well child visit, the "Assessment/Plan" portion of the record states, "He is doing well…. With recent platelet count being low (he has ITP and being followed by Children's), we are going to hold on vaccinations. Mother not comfortable. Will get hematologist opinion on when to give vaccinations." Ex. 6 at 3. Although this record does not contain the opinion of a doctor indicating s/he believes the vaccinations were causal, it does constitute some limited evidence that treatment options were discussed and a consensus was reached to withhold further vaccination until Petitioners could consult with a hematologist.

Based on my review of all the evidence I find that one or more of K.W.'s vaccinations did cause his ITP. I find that the onset of K.W.'s viral infection was outside the causality window discussed by the experts and the medical literature. More importantly, the relative proximity of K.W.'s vaccinations to his ITP when compared to that of his viral illness further supports a logical sequence of cause and effect. In this case the disease onset occurred within the peak exposure to onset period for the vaccines, and outside the very remote end of the period from onset of the virus. Petitioner has established *Althen's* second prong.

3. *Althen* Prong 3

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, he must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Human Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

a. *K.W. Developed ITP Nine Days After Vaccination*

It is not in dispute that K.W.'s symptoms of ITP began on July 25, 2014, or nine days after his July 16, 2014 vaccinations. Ex. 6 at 7 (Dr. Payne noted on July 30, 2014 that "Parents report pt has had several new bruises over the last 6 days with no known trauma"). K.W.'s medical records from July 31, 2014 reflect a similar notation. *See* Ex. 4 at 150 (Dr. Russo wrote "mother

states that she began to notice "a lot of bruising" this past Friday [July 25, 2014]").

*b. Nine Days Post-Vaccination is a Temporally-Appropriate Onset Interval*

Onset of ITP following vaccination is thought to occur in the days to weeks following vaccination. O'Leary notes that when assessing the risk of ITP after vaccination, the vaccine-exposed period is defined as 42 days post vaccination. O'Leary at 3. In support of this general timeframe, Dr. Forman wrote, "It is known that ITP generally occurs between one and four weeks after a viral infection or immunization, with a peak incidence between one and two weeks." First Forman Rep. at 3.

Of note, under 42 C.F.R. § 100.3(a)(V)(A), in order to satisfy the Table requirement for ITP following MMR vaccine, vaccination to onset of symptoms must occur within seven to 30 days. Thus, the Vaccine Table also provides some support for the proposition that onset of ITP nine days after vaccination (generally) is medically appropriate.

Respondent contends that Petitioners have not established the third *Althen* prong. Respondent asserts that K.W. should have developed ITP sooner than nine days after vaccination because he had received each of the vaccines before and thus should have experienced a booster effect.

*c. Booster Effect*

With respect to this issue, Dr. Gill opined that "if one of the vaccines [K.W.] received was a cause of [K.W.'s] ITP, K.W's thrombocytopenia and bruising should have occurred sooner due to a booster effect." Gill Rep. at 4. In her report, Dr. Gill wrote that production of antibodies in response to a vaccine generally takes a minimum of 10-14 days with the first exposure; however, re-exposure to the antigen, as in the case of multiple exposures to a vaccine generates higher antibody levels within 24-48 hours. *Id.* at 3. However, this statement does not explain, for example, why the Vaccine Table provides that between seven and 30 days is an acceptable time period for manifestation of onset after MMR vaccine, without reference to whether the vaccine was an initial shot or a booster dose. 42 C.F.R. § 100.3(a)(V)(A).

Initially, Dr. Strouse concurred with Dr. Gill's assessment. In his first expert report, Dr. Strouse wrote: "I concur with the diagnosis of primary autoimmune thrombocytopenia, but find the time of onset to be most consistent with [the] recent viral infection in late June 2014 as immune mediated thrombocytopenia associated with the 4th doses of vaccines would most likely to have developed in a shorter period of time because of the booster effect of the multiple doses of vaccine." First Strouse Rep. at 2. Notably, in his second report, when specifically asked by me whether booster responses result in a shortened interval between repeat exposure to an antigen and onset of ITP symptoms, he wrote: "There is inadequate published evidence to support or refute this hypothesis in relationship to repeated vaccination." Second Strouse Rep. at 1.

Dr. Forman does not agree with Dr. Gill with regard to this issue. He states, "[a]mnestic (booster) responses do not require a shortened interval between a repeat exposure to an antigen and the onset of ITP symptoms." Third Forman Rep at 1. He goes on to state that there is no

evidence in the medical literature indicating that a shortened interval between vaccine and bruising is required. *Id.*

While recall responses to vaccines may occur more quickly to booster doses than to the primary doses as discussed by Dr. Gill, there is not sufficient evidence in the record that they have to occur within a 24 to 48 hour time period. I find, in accordance with Dr. Forman's report and Dr. Strouse's second report, that there is not sufficient evidence to suggest that K.W.'s immune response should have occurred sooner than nine days post vaccination.

Based on the above-mentioned medical literature and expert opinions, I find that ITP can occur any time between one to four weeks following immunization. As both Petitioners and Respondent agree that K.W.'s ITP occurred nine days after his immunization, I find that the onset of his ITP occurred in a medically-appropriate onset interval after his vaccinations. Petitioners have met *Althen* Prong 3.

**D. Alternate Causation**

When Petitioners establish the *Althen* prongs, the burden shifts to the Respondent to establish an alternative explanation for the condition affecting the vaccinee by a preponderance of the evidence. *Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). To satisfy his burden, Respondent is required "not only to prove the existence of a factor unrelated, but also to prove by a preponderance of the evidence that the factor unrelated actually caused the alleged injury." To do so, Respondent must "provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury." *de Bazan*, 539 F.3d at 1354.

Here, the Respondent's brief does not argue that K.W.'s URI is an alternate cause of his ITP, but rather that the existence of the URI prevents Petitioners from meeting their burden of proof. *See* Resp.'s Brief at 15, 18-19. *See also Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (stating that "[o]ur decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the "factors unrelated" defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question").

However, in their expert reports, Dr. Gill and Dr. Strouse raise the issue of alternate causation. Dr. Gill wrote that "to a reasonable degree of medical probability, K.W. developed ITP because of a preceding viral infection and not one [of] the vaccines that he received on July 16, 2014." Gill Rep. at 4. Similarly, Dr. Strouse stated, "it is far more likely that the true cause of his ITP was the recent respiratory viral infection". Second Strouse Rep. at 2. For the reasons articulated earlier in this ruling, just as these opinions do not prevent Petitioners from meeting their burden of proof, I likewise do not find this evidence sufficient to meet Respondent's burden to demonstrate that K.W.'s viral infection was an alternate cause of his ITP.

## VII. Conclusion

Based on the foregoing, I conclude that Petitioners have met their burden of proof under *Althen*, and furthermore, that Respondent has not demonstrated that K.W.'s viral infection was an alternate cause of his ITP. Petitioners are entitled to compensation. An order regarding damages will issue shortly.

**IT IS SO ORDERED.**

**s/ Katherine E. Oler**
Katherine E. Oler
Special Master